 1842-0024

REMARKS

Consideration of the present application as amended is requested. The pending claims were rejected under obviousness-type double patenting. Applicants will submit an appropriate terminal disclaimer to overcome this rejection once the claims are found to be patentable over the prior art.

All of the claims were rejected over the primary reference to Ray (WO99/02214). Specifically, claims 33-42, 45-64, 66-76, 78-82 and 84-91 were rejected as anticipated by Ray, while the remaining claims (43, 44, 65 and 83) were deemed obvious in view of the combination of Ray with the patent to Fischer (No. 4,114,329).

It is first noted that no prior rejection was lodged against claim 77. It is therefore assumed that this claim would be allowable once the obviousness-type double patenting rejection is addressed.

Turning first to the independent method claims 33 and 45, it was suggested that the steps of these claims would be inherently carried out by the device disclosed in Ray. New claim 92 has been introduced to replace claim 33. Both method claims 92 and 45 concern directing fluid into the disc space between vertebrae. On the other hand, Ray concerns reforming a collapsed vertebra, so all of the activity occurs within a vertebra. Thus, any steps inherently carried out by the Ray device will occur in the vertebral body and not in the disc space, as required by Applicants' claims. In fact, the Ray publication describes a method for reforming a collapsed vertebra in the first paragraph on page 9. Thus, all of the steps occur in the vertebral body.

Ray cannot anticipate Applicants' claim 92 because the Ray device is not used in the disc space. Moreover, Ray does not disclose or contemplate the claimed steps of creating an opening in the annulus fibrosus of the disc, removing at least a portion of the nucleus pulposus, or introducing fluent material in contiguity with the disc annulus and remaining nucleus. Significantly, Ray does not disclose or contemplate removing ***any*** material from the collapsed vertebra since removal of vertebral bone would be contrary to the purpose of the Ray apparatus and method, namely to restore a collapsed vertebra.

Ray also fails to disclose the last step of Applicants' method claim 92, namely allowing the fluent material to substantially cure while maintaining the seal. Ray discloses filling the cavities left after the expansion balloons are deflated and then

removing the introducers (and thereby the sealing member 24b) from the vertebral body. Ray, p. 18, lines 11-14. Instead the patient is maintained in traction as the "setting process proceeds to completion" (Ray, p. 18, lines 15-17) in order to overcome the "collapsing force imparted on the vertebrae" (Ray, p. 16, lines 3-7). Thus, the seal is not maintained while the fluent material substantially cures, as is claimed. Furthermore, as shown in FIG. 2, the auger-like tips 22 of the introducers 20 extend into the vertebral body and would leave a cavity in the repaired bone if the introducers were left in place while the repair material cures.

With respect to independent method claim 45, the Ray publication does not and cannot anticipate this claim because it fails to disclose creating an opening in the disc annulus, distracting the vertebral bodies flanking the disc, or maintaining a seal and the pressure while the injected biomaterial is cured. First, as explained above, the Ray system and method is intended for restoring a collapsed vertebral body, and is therefore not disclosed for use in the intervertebral disc. Thus, there is no disclosure or suggestion of accessing the intradiscal space through an opening in the disc annulus fibrosus.

Second, since the Ray system is not intended for use in the disc, there is no disclosure for distracting to approximate the natural disc height. Distraction requires applying force to the two vertebrae above and below the disc, which necessarily requires a viable, non-collapsed vertebral body. The Ray system is used when a collapsed vertebra exists, so there is no teaching or suggestion for distracting the vertebral bodies as required in Applicants' claim 45.

The last step of the method of claim 45 is similar to the last step of the method claim 92 discussed above. In particular, this step requires maintaining the seal through which the curable biomaterial is injected into the intradiscal space, throughout the period for substantially curing the biomaterial. As explained above, the Ray publication does not disclose maintaining the auger-like tips of the introducers with the sealing member 24b thereon within the vertebral body space, but instead states that the introducers are removed. In the case of the present invention, the biomaterial when cured exerts sufficient pressure against the adjacent vertebrae to emulate the physiology and function of a natural disc nucleus. Thus, the curable material is maintained under some pressure during curing to exhibit the appropriate properties of the nucleus pulposus once cured.

The Ray system contemplates that the material injected into the vertebral body will harden, while the biomaterial injected into the disc space in accordance with the present invention provides nucleus pulposus properties after curing, while also restoring the anatomic disc height. In order to accomplish both functions, the biomaterial is allowed to cure under pressure, which means that the seal must be maintained during curing. The nature of the vertebral body repair disclosed in the Ray publication does not require this step. Therefore, there is no disclosure or suggestion in Ray for maintaining the seal while the injected material substantially cures.

Since Ray doesn't disclose (either directly or inherently) every limitation of method claims 92 or 45, it cannot anticipate. Moreover, since there is no suggestion to modify Ray in the manner suggested by Applicants' claims, Ray fails to establish a prima facie case for obviousness of these claims. Thus, method claims 92 and 45, along with their dependent claims 34-44 and 46-47, 49 and 51-53 are believed to be patentable over the Ray publication.

The dependent method claims are also distinguishable on their own merits. For example, dependent claim 39 defines a cannula for assisting in introducing the fluent material in which the cannula is configured to distract the vertebrae on opposite sides of the disc upon placement of the cannula in the opening in the disc annulus. Since the Ray patent does not concern an intradiscal method or system it does not disclose or contemplate distracting the intradiscal space between successive vertebrae. The Ray publication illustrates an auger-type tip that is configured to be threaded through the cortical bone of the vertebral body. There is no suggestion to, nor would there be any reason to, modify this auger-type tip into a configuration for distracting a disc space between two vertebrae.

Dependent claim 42 indicates that the curable material is introduced under pressure and that the pressure is maintained until the biomaterial has cured. As indicated above, it is believed that the Ray application fails to disclose maintaining a seal while the injected material is cured. Thus, there is nothing in Ray that discloses or suggests maintaining the injected material under pressure, as recited in claim 42.

Dependent claims 43 and 44 were rejected as obvious in view of the combination of Ray with the patent of Fischer. The Fischer patent concerns an apparatus for securing

objects to support structures. It is clearly not within the field of medicine, orthopaedics or spinal disc repair. Thus, the Fischer patent is non-analogous art and not within the type of art that would normally be consulted by a person of ordinary skill in the medical field of spinal surgery. Furthermore, even if Fischer can be properly combined with the spinal repair system of Ray, there is no motivation for such a combination. The vent in Fischer is "for venting of air entrapped in the clearance with is being displaced by the hardenable material." Fischer, col. 2, lines 53-58. Moreover, the present invention concerns restoring a collapsed disc space. As recited in claim 44, the vent allows the biomaterial to seep out, thereby providing a visual indication to the surgeon that the disc space has been completely filled. There is nothing in the Ray publication to suggest adding this feature to the Ray procedure. Thus, claims 43 and 44 are believed to be non-obvious over the cited combination of Ray and Fischer.

Independent device claims 54, 66, 73 and 80 were rejected as anticipated by the Ray application. Claim 66 and its dependent claims 67-68 have been canceled so their rejection is moot. Independent claim 54 has been amended to include a vent through the seal of the device for sealably introducing fluent material into a disc space. As explained above, the Fischer patent was combined with the Ray publication because Fischer is alleged to disclose vented introduction of a hardenable material into a mechanical support structure. However, Fischer is non-analogous art and not properly combinable with the Ray publication. Moreover, even if Fischer may be properly considered, there is no motivation to add the Fischer vent to the Ray device. Thus, independent claim 54 and its dependent claims 55-65 and 69-72 are believed to be patentable over the cited references.

It can also be pointed out that the dependent claims define features not found in the Ray reference. For instance, dependent claim 60 defines the cannula as configured to distract the adjacent vertebrae. As explained above, Ray does not disclose or contemplate distraction of the vertebrae on opposite sides of a spinal disc. Claim 61 defines the seal as configured for disposition within the opening in the disc annulus. The seal 24b in Ray resides between the flange 24 and the outside of the vertebral body. Ray, p.1 2, lines 8-13. There is no motivation to reconfigure the seal 24b in Ray so that it can be disposed within the hole in the vertebral bone. Claim 70 is now dependent from claim 54 by virtue of the amendment to claim 69. This claim defines the insertion tip as being

separable from the cannula used to introduce the fluent material into the disc space. The introducer 20 in Ray is depicted as having the auger tip integral with the introducer. There is no disclosure or motivation for removing the auger tip 22 from the Ray introducer since the tip is not left behind in the vertebral body. Thus, there is nothing in Ray that suggests the removable insertion tip defined in Applicants' claim 71.

Independent claim 73 defines a device with a shape adapted to distract a disc space. This claim was rejected as anticipated by the inflatable balloons of Ray. In order to more clearly define the claimed invention, claim 73 has been amended to indicate that the device has a substantially rigid body with a shape adapted to distract the disc space. This is in contrast to the inflatable balloons shown in Ray. There is no disclosure or suggestion in Ray for providing a rigid body that is shaped to distract a disc space. The balloons in Ray are intended to compact the cancellous bone within the damaged vertebral body and creating a space to be filled to repair the bone. The resulting space in the vertebral bone is necessarily much larger than the insertion tool, as shown in FIGS. 2 and 5 of Ray. Thus, any substantially rigid body capable of performing the same function in Ray would have to be nearly as big as the vertebral body itself. Of course, the opening that must be formed in the vertebral body to accommodate such a body would cause even more damage to the integrity of the vertebral body. Thus, there is no motivation to replace the inflatable balloons of Ray with a substantially rigid body capable of distracting a disc space, and in fact such a modification would appear to frustrate the purpose of the Ray device.

There is no disclosure or suggestion in Ray of a substantially rigid body formed to distract a disc space that includes a passageway for accessing the disc space, as defined in independent claim 73. Thus, it is believed that claim 73 is patentable over Ray, along with its dependent claims 74-79.

The last independent claim 80 to a kit of parts was also rejected as anticipated by Ray. Claim 80 has been amended to define the curable material as having, upon curing, properties substitutive of the nucleus pulposus of a disc. The Ray patent discloses a ***hardenable material*** that is intended to substitute for the bone of a vertebral body. Ray does not disclose any disc nucleus substitute or replacement material. The bone substitute material of Ray would clearly not emulate the properties of the disc nucleus,

which are elastic in nature. Thus, it is believed that kit claim 80 and its dependent claims 81-91 are patentable over the Ray patent.

In view of the foregoing arguments and amendments it is believed that this application is in condition for allowance. The pending claims after amendment are 34-40, 42-47, 49, 51-65, 69-91 and new claim 92. Withdrawal of the prior art rejections is requested, in response to which Applicants' will submit an appropriate terminal disclaimer to address the obviousness-type double patenting rejection.

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